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Kindly enter the following amendments:

***In the claims:***

15 Please cancel the previous claims 1 – 17, 25, 33 and 34 without prejudice and disclaimer.

**Previous claims 1 – 17, 25,33 and 34:**

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1 An improved method of hormonal treatment of breast cancer and said hormonal treatment comprising of breast implants of anti-estrogens and steroid hormones, or its synthetic derivatives in one or more slow release formulations and permitting said drugs to be continuously released at near constant rate directly to the breast for longer periods with minimal or no  
25 systemic toxicity.

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2 A method according to claim 1 further comprising release of said anti-estrogen and hormonal compositions to the breast for extended periods by diffusion and biodegradation from said breast implants in sufficient amounts  
30 to saturate the binding sites for said drug compositions in the breast and to exert their maximum tumor control activity.

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- 3 A method of claim 1 wherein said implants comprising of hormonally  
effective compositions selected from the anti-estrogen groups consisting of  
tamoxifen, raloxifene and toremifene, and from the hormonal groups  
5 consisting of progesterones and corticosteroids.
- 4 A method according to claim 1 wherein said prostatic implants of said drug  
compositions are made as separate or in combination thereof.
- 10 5 The method of claim 1 wherein said breast implants are made as  
biodegradable fused combinations of said therapeutic drug compositions and a  
lipoid carrier and said fused implants containing a single or multiples of said  
drug formulations for their slow release direct to breast.
- 15 6 A method according to claim 1 wherein said breast implants are made of  
Silastic capsules containing said therapeutic drug compositions as separate or  
in combination thereof for said formulation's slow release direct to breast.
- 20 7 The method of claim 1 wherein said breast implants are made as injectable  
microcapsules prepared from biodegradable polymer and said microcapsules  
containing said therapeutic drug compositions as separate or as in combination  
thereof for injection to the breast as slow release implant.

8 The method of claim 7, wherein said prostatic implants are made as injectable microcapsules prepared from biodegradable polymer and said microcapsules containing said therapeutic drug compositions dispensed in sterile liquid medium in sterile syringe for direct prostatic injection as slow release implant.

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9 The method of claim 7, wherein said breast implants are made as injectable microcapsules prepared from biodegradable polymer and said microcapsules containing said therapeutic drug compositions dispensed in a mixture of sterile liquid mediums like normal saline, a local anesthetic and ethanol in a sterile  
10 syringe for direct injection to the breast as chelating slow release formulations when it comes in contact with breast tissue.

10 The method of claim 1 wherein said breast implants are selected from readily available commercial pharmaceutical preparations of anti-estrogens steroid  
15 hormones or their derivatives and said implants containing a single or multiples of said drug formulations for their slow release direct to the breast.

11 An improved method of concomitant hormonal and radiation treatment of the breast cancer and said hormonal treatment comprising of breast implants of  
20 anti-estrogens and steroid hormones in one or more slow release formulations and permitting said drugs to be continuously released at near constant rate directly to the breast during the radiation therapy and afterwards for longer periods.

12 An improved method of concomitant hormonal and radiation treatment of the breast cancer according to claim 11, wherein said continued slow release of hormonal composition directly to the breast during the interstitial radioactive seeds implants and afterwards for longer periods.

13 An improved method of concomitant hormonal and radiation treatment of breast cancer according to claim 11, wherein said hormonal implants to the breast is performed concomitantly with the radioactive implants to improve cure and convenience to patient than when they are implanted separately.

14 An improved method of treating hormone dependent and hormone refractory breast cancer and its accessible metastasis by implanting combinations of hormones and anti-estrogens to said tumor sites for improved tumor control with lesser toxicity than by administering said hormonal compositions at higher doses by mouth, subcutaneous, intramuscular or intravenous routes and said hormone compositions containing in one or more slow release implant formulations.

15 A method of claim 14, wherein said breast, subcutaneous or intramuscular hormonal implants methods comprising implanting single or synergetic combination of hormonally and cytotoxically effective compositions selected from the anti-estrogen groups consisting of tamoxifen, raloxifene and

toremifene and from the hormonal groups consisting of iodo-estradiol, progesterones, corticosteroids and they are fused with a lipid carrier or encapsulated in Silastic capsules or formulated as injectable microcapsules as suitable slow-release breast, subcutaneous or intramuscular implant.

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16 A method of claim 14, wherein said slow-release breast implant of anti-estrogen and hormonal compositions for treating breast cancer and providing minimum or no toxicity as compared to when said drug compositions are administered by oral routes daily.

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17 A method of claim 14, wherein high concentrations of said drug composition to the breast is achieved by implanting said formulations directly to the breast and to derive the added beneficial effect from these breast implants on breast cancer by inhibiting the hypothalamic-pituitary LHRH, FSH and LH secretion by these composition's systemic contents.

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25 Anticancer products of claim 18, wherein said single or synergetic combinations of hormonally and cytotoxically effective amounts of an anti-estrogen from the groups of tamoxifen, raloxifene, or toremifene and a progesterone composition selected from the group consisting of megestrol acetate, medroxyprogesterone, norethindrone acetate norgestrel and from the corticosteroids group prednisolone in same or separate slow release Silastic capsules suitable for prostatic implantation.

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33 A method and product of claim 32, wherein said hormone implant treatment of breast cancer is less-costly, less toxic and more convenient to the patient.

5 34 A method and product of claim 32, wherein said slow-release anti-estrogen implant treatment of the breast as hormonal prophylaxis against developing breast cancer by saturation of the breast tissue's binding sites for said anti-estrogens with high efficiency than by said anti-estrogen's daily oral administration at higher doses.

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***In the claims:***

Clean version incorporating all changes

15 **Claims replacing the original claims 1 – 17, 25, 33 and 34**

35. A method of minimal or no toxic primary hormonal treatment of breast cancer about one thousand dollars of drug's cost for five years treatment as compared to the present cost of about 20-35,000 dollars for similar five years treatment for said hormonal treatment of breast cancer comprising of breast implants of anti-estrogens and steroid hormones and their synthetic derivatives as fused with a lipid carrier or as encapsulated in Silastic capsules or as injectable

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microcapsules which are suitable for breast implantation such that said hormonally and cytotoxically effective compositions are continuously released at rates of 50 to 100  $\mu\text{g}$  per day directly to the breast to saturate the estrogen and steroid hormone binding sites in breast cancer to inhibit tumor growth and to minimize the systemic toxicity caused by administration of said drugs by oral, subcutaneous, intramuscular or intravenous routes at much higher daily doses ranging from 1 to 60 mg.

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36. A method of minimal or no toxic hormonal treatment of breast cancer at much reduced cost according to claim 35, wherein said implants releases 50 – 100  $\mu\text{g}$  of its hormonal compositions to the breast for extended periods of one to five years from one such implant by diffusion and biodegradation that saturates the said drug's binding sites in the breast and breast cancer to exert its maximum tumor control activity.

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37. A method of minimal or no toxic hormonal treatment of breast cancer at much reduced cost of claim 35, wherein said implants comprising of anti-estrogen and hormonally effective compositions selected from the anti-estrogen groups consisting of tamoxifen, raloxifene and toremifene, and from the hormonal groups consisting of progestones, fluoxymesterone, corticosteroids and iodo-estradiol.

38. A method of minimal or no toxic hormonal treatment of breast cancer at much reduced cost according to claims 35, wherein breast implants of said drug compositions are made as single drug formulation from any one of the drugs from a group consisting of tamoxifen, raloxifene and toremifene, or from the hormonal group consisting of progesterones, fluoxymesterone, iodoestradiol, or two drug combinations one comprising of an anti-estrogen from the group of tamoxifen, raloxifene and toremifene, another comprising from the hormonal groups consisting of progesterones, prednisolone, fluoxymesterone, iodoestradiol, or as synergetic three drugs combinations as one from the group of anti-estrogens such as tamoxifen, raloxifene and toremifene, another from the group of progesterones and a third from the group of prednisolone, fluoxymesterone, iodoestradiol.

39. The method of minimal or no toxic hormonal treatment of breast cancer at much reduced cost of claim 35, wherein said breast implants are made as biodegradable fused combinations of said therapeutic drug compositions and a lipoid carrier and said fused implants containing a single or multiples of said drug formulations for their slow release at a rate of 50 – 100  $\mu$ g direct to the breast and to breast cancer for one to five years from one such implant for to inhibit hormone dependent tumor growth and to minimize the systemic toxicity caused by administration of higher doses of said drugs by oral, subcutaneous, intramuscular or intravenous routs at much higher doses ranging from daily 1 to 60 mg to treat breast cancer.



40. A method for minimal or no toxic effects of hormonal treatment of breast cancer at much reduced cost with lesser toxicity according to claim 35, wherein said breast implants are made of Silastic capsules containing said drug composition as single drug formulation made from any one of the drugs from a group consisting of tamoxifen, raloxifene and toremifene, or from the hormonal group consisting of progesterones, fluoxymesterone, iodoestradiol, or two drug combinations one comprising of an anti-estrogen from the group of tamoxifen, raloxifene and toremifene, another comprising from the hormonal group consisting of progesterones, prednisolone, fluoxymesterone, iodoestradiol, or as synergetic three drugs combinations as one from the group of anti-estrogens such as tamoxifen, raloxifene and toremifene, another from the group of progesterones and a third from the group of prednisolone, fluoxymesterone, iodoestradiol for said formulation's slow release at a rate of 50-100  $\mu$ g direct to the breast and breast cancer for one to five years from one such implant for hormonal treatment of breast cancer.

41. A method for minimal or no toxic effects of hormonal treatment of breast cancer at much reduced cost of claim 35, wherein said breast implants are made as microcapsules prepared from biodegradable polymer and said microcapsules containing said therapeutic drug composition as single drug formulation made from any one of the drugs from a group consisting of tamoxifen, raloxifene and toremifene, or from the hormonal group consisting

of progesterones, fluoxymesterone, iodoestradiol, or two drug combinations one comprising of an anti-estrogen from the group of tamoxifen, raloxifene and toremifene, another comprising from the hormonal group consisting of progesterones, prednisolone, fluoxymesterone, iodoestradiol, or as synergetic three drugs combinations as one from the group of anti-estrogens such as tamoxifen, raloxifene and toremifene, another from the group of progesterones and a third from the group of prednisolone, fluoxymesterone, iodoestradiol for said formulation's slow release at a rate of 50-100  $\mu$ g direct to the breast and breast cancer for one to five years from one such implant for hormonal treatment of breast cancer.

42. The method of minimal or no toxic hormonal treatment of breast cancer at much reduced cost of claim 35, wherein said breast implants are made as injectable microcapsules prepared from biodegradable polymers and said microcapsules containing said therapeutic drug compositions dispensed in sterile liquid medium in sterile syringe for direct injection to the breast and breast cancer for slow release of said drugs at a rate of 50-100  $\mu$ g daily direct to the breast and breast cancer for one to five years from one such implant for hormonal treatment of breast cancer.

43. The method of minimal or no toxic hormonal treatment of breast cancer at much reduced cost of claim 35, wherein said breast implants are made as injectable microcapsules prepared from biodegradable polymers and said

microcapsules containing said therapeutic drug compositions are dispensed in a mixture of sterile liquid mediums like normal saline, a local anesthetic and ethanol in a sterile syringe for direct injection to the breast and breast cancer as chelating slow release formulations of said drugs when in contact with breast tissue for the release of said drugs at a rate of 50-100  $\mu$ g daily direct to the breast and breast cancer for one to five years from one such implant for hormonal treatment of breast cancer.

44. The method of minimal or no toxic hormonal treatment of breast cancer at much reduced cost of claim 35, wherein said breast implants are selected from readily available commercial pharmaceutical implant preparations made from any one of the drugs from a group consisting of tamoxifen, raloxifene and toremifene, or from the hormonal group consisting of progesterones, fluoxymesterone, iodoestradiol, or two drug combinations one comprising of an anti-estrogen from the group of tamoxifen, raloxifene and toremifene, another comprising from the hormonal group consisting of progesterones, prednisolone, fluoxymesterone, iodoestradiol, or as synergetic three drugs combinations as one from the group of anti-estrogens such as tamoxifen, raloxifene and toremifene, another from the group of progesterones and a third from the group of prednisolone, fluoxymesterone, iodoestradiol for said formulation's slow release at a rate of 50-100  $\mu$ g direct to the breast and breast cancer for one to five years from one such implant for hormonal treatment of breast cancer.

45. A method for minimal or no toxic effects from hormonal treatment of breast cancer at less than 5 percent cost of the present day hormone treatment of breast cancer when hormone treatment is combined with radiation therapy and to continue the hormone treatment after radiation for periods of one to five years by breast implants of hormone as single drug formulations from the drug group consisting of tamoxifen, raloxifene and toremifene, or from the hormone group consisting of progesterones, fluoxymesterone, iodoestradiol, or two drug combinations one comprising of an anti-estrogen from the group of tamoxifen, raloxifene and toremifene, another comprising from the hormonal group consisting of progesterones, prednisolone, fluoxymesterone, iodoestradiol, or as synergetic three drugs combinations as one from the group of anti-estrogens such as tamoxifen, raloxifene and toremifene, another from the group of progesterones and a third from the group of prednisolone, fluoxymesterone, iodoestradiol for said formulation's slow release at a rate of 50-100  $\mu$ g direct to the breast and breast cancer for one to five years from one such implant and implanted before the start of radiation therapy for combined radiation and hormone treatment of breast cancer and its continued hormonal treatment after completion of radiation therapy for periods of one to five years with minimal systemic toxicity from such hormone treatment of breast cancer as an alternative to administration of said drugs by daily oral, subcutaneous, intramuscular or intravenous routs at much higher doses ranging from 1 to 60 mg and to maintain the cost of said implants preparations

at less than 5 percent of the cost of present day hormone treatment of breast cancer.

46. A method for minimal or no toxic hormone treatment of breast cancer at much  
5 reduced cost according to claim 45, wherein hormone treatment is combined  
with interstitial radiation therapy and said hormone is released directly to the  
breast and breast cancer slowly at a daily rate of 50 – 100  $\mu$ g during the  
extended course of interstitial radiation by interstitial radioactive seeds  
implants and thereafter for periods of one to five years from one such implant  
10 and thereby minimizing the systemic toxicity of hormone treatment of breast  
cancer as an alternative to administration of said drugs by oral, subcutaneous,  
intramuscular or intravenous routes at much higher doses ranging from 1 to 60  
mg and higher and at less than 5 percent of the cost of present hormone  
treatment of breast cancer.

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47. A method for minimal or no toxic hormone treatment of breast cancer at much  
reduced cost according to claim 45, wherein hormone implant treatment  
combined with interstitial radiation as a single procedure to minimize patient's  
hospitalization and improve patient's comfort and said hormone is released  
20 directly to the breast and breast cancer slowly at a daily rate of 50 – 100  $\mu$ g  
during the course of external radiation and thereafter for periods of one to five  
years from one such implant and thereby to minimizing the systemic toxicity  
of hormone treatment of breast cancer as an alternative to daily administration

of said drugs by oral, subcutaneous, intramuscular or intravenous routes at much higher doses ranging from 1 to 60 mg and which is less than 5 percent of the cost of present day hormone treatment of breast cancer.

- 5           48. An implant method of hormones and their derivatives for treating hormone dependent and hormone refractory breast cancer and its accessible metastasis for tumor growth suppression at less than five percent of such treatments present costs and said hormone implants selected as single drug formulations from the group consisting of tamoxifen, raloxifene and toremifene, or from
- 10           the hormone group consisting of progestones, fluoxymesterone, iodoestradiol, or two drug combinations one comprising of an anti-estrogen from the group of tamoxifen, raloxifene and toremifene, another comprising from the hormonal group consisting of progestones, prednisolone, fluoxymesterone, iodoestradiol, or as synergetic three drugs combinations as
- 15           one from the group of anti-estrogens such as tamoxifen, raloxifene and toremifene, another from the group of progestones and a third from the group of prednisolone, fluoxymesterone, iodoestradiol for said drug's slow release by biodegradation and diffusion at a daily rate of 50-100  $\mu$ g for periods of one to five years from one such implant and to saturate the receptor
- 20           binding sites in tumor cells for such implanted hormones to exert their cytotoxic activity for extended periods of one to five years with minimal or no systemic toxicity as an alternative to daily administration of said drugs by

oral, subcutaneous, intramuscular or intravenous routs at much higher daily doses ranging from 1 to 60 mg.

49. An implant method of hormones and their derivatives of claim 48 for  
5       continuous daily treatment of hormone dependent and hormone refractory  
breast cancer and its accessible metastasis for tumor growth suppression with  
hormones and their derivatives at a daily dose of 50-100  $\mu$ g delivered directly  
to tumor for periods of one to five years from one such implant by diffusion  
and biodegradation of implanted compositions, implanting said compositions  
10       as single or synergetic combination of hormones and their derivatives and said  
drugs are selected from the anti-estrogen groups consisting of tamoxifen,  
raloxifene and toremifene and from the hormonal groups consisting of iodo-  
estradiol, progesterones, corticosteroids and they are fused with a lipoid  
carrier or encapsulated in Silastic capsules or formulated as injectable  
15       microcapsules as suitable slow-release drug compositions by biodegradation  
and diffusion as an alternative to daily administration of said drugs by oral,  
subcutaneous, intramuscular or intravenous routs at much higher daily doses  
ranging from 1 to 60 mg and at less than 5 percent of the cost of present day  
hormone treatment of breast cancer.

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50. An implant method of hormones and its derivatives of claim 48 for continuous  
daily treatment of hormone dependent and hormone refractory breast cancer  
and its metastasis, wherein said implants providing effective tumor control by

continued saturation of hormone binding receptor sites in tumor with one or more of such compositions and at a daily dose of 50-100  $\mu\text{g}$  delivered directly to tumor for periods of one to five years from one such implant by diffusion and biodegradation of said implanted compositions as an alternative to daily administration of said drugs by oral, subcutaneous, intramuscular or intravenous routes at much higher daily doses ranging from 1 to 60 mg with their associated higher toxicity and over ninety five percent increased cost.

51. An implant method of hormones and their derivatives of claim 48 for continuous daily treatment of hormone dependent and hormone refractory breast cancer and its metastasis for one to five years periods, wherein said implants providing effective tumor control by continued saturation of hormone binding receptor sites in the tumor with one or more of such implanted compositions and said hormones and their derivatives are directly delivered to the tumor at a daily dose of 50-100  $\mu\text{g}$  for periods of one to five years from one such implant by diffusion and biodegradation of said implanted compositions and combined with inhibition of hypothalamic-pituitary LHRH, FSH and LH secretion by these composition's systemic contents during such implant's effective period ranging from one to five years

52. Anti-cancer products of claim 18, wherein said single or synergetic combinations of hormonally and cytotoxically effective amounts of an anti-estrogen from the groups of tamoxifen, raloxifene, or toremifene and a



progesterone composition selected from the group consisting of megestrol acetate, medroxyprogesterone, norethindrone acetate norgestrel and from the corticosteroids group prednisolone in same or separate slow release Silastic capsules suitable for breast implantation.

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53. Slow release hormonal breast implant method and products of claim 32, wherein said one hormonal implant preparation delivers hormone treatment of breast cancer for one to five years and for said one to five years hormone treatment costing only about one thousand dollars as compared to the present day cost of about 20-35,000 dollars for similar five years treatment with said hormones and their derivatives by oral, subcutaneous, intramuscular or intravenous routs at much higher daily doses ranging from 1 to 60 mg to treat breast cancer for similar five years and hence less systemic toxicity than by administration of said drugs at such high doses.

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54. A method and product of claim 32, wherein said slow-release anti-estrogen implant treatment to the breast as chemoprevention of breast cancer with lesser cost and toxicity than those reported before.

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